

Improving the Quality of Dentistry (IQuaD): a cluster factorial randomised controlled trial comparing the effectiveness and cost-benefit of oral hygiene advice and/or periodontal instrumentation with routine care for the prevention and management of periodontal disease in dentate adults attending dental primary care

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Scientific summary

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Scientific summary

Background

Periodontal disease is an inflammatory disease that affects the soft and hard tissues supporting teeth. This disease is largely preventable, yet it remains the major cause of poor oral health worldwide and is the primary cause of tooth loss in older adults. Severe periodontitis is the sixth most prevalent human disease, with a standardised prevalence of 11.2%.

The categorisation of periodontal disease is based on which of the tissues surrounding and supporting the teeth are affected and is classified into two broad categories: (1) gingivitis and (2) periodontitis. Gingivitis is a reversible condition characterised by inflammation and bleeding at the gingival margin. The gum becomes swollen and red because of the inflammation and will bleed easily on probing. It is a prerequisite for periodontitis and a risk indicator for caries progression. Periodontitis is the irreversible destruction and loss of the supporting periodontal structures (periodontal ligament, cementum and alveolar bone). The result can be unsightly gingival recession, sensitivity of the exposed root surface, root caries (decay), mobility and drifting of teeth and, ultimately, tooth loss.

Individuals and dental care professionals have different roles to play in the prevention and management of periodontal disease. Effective individual self-care (tooth brushing and interdental aids) for plaque control is considered the foundation stone of successful periodontal prevention and therapy of disease. The current annual public spend on oral care products in the UK alone is £950M. Dental care professionals' role in prevention and periodontal treatment involves providing patients with oral hygiene advice (OHA) (self-care) and periodontal instrumentation (PI), often known as 'scale and polish'. There is no agreed published content of OHA but the overall aim is to encourage effective self-care. PI comprises removal of plaque and plaque retentive factors [e.g. calculus (tartar) deposits] which, together with the removal of overhanging restorations (poorly adapted dental fillings), facilitates adequate patient-performed oral self-care. In the UK, almost all of this treatment is provided by general dental practitioners and dental hygienists/therapists in primary care.

Despite evidence of an association between sustained, good oral hygiene and a low incidence of periodontal disease and caries in adults, there is a lack of strong and reliable evidence to inform clinicians of the relative clinical effectiveness (if any) of different types of OHA that can be delivered in a dental setting.

The evidence to inform clinicians of the effectiveness and optimal frequency of PI is mixed. A Cochrane systematic review (Worthington HV, Clarkson JE, Bryan G, Beirne PV. Routine scale and polish for periodontal health in adults. *Cochrane Database Syst Rev* 2013;**11**:CD004625) of routine PI for periodontal health in adults found insufficient evidence to determine the effects of routine PI treatments, providing little guidance for policy-makers, dental professionals or patients.

There was therefore an urgent need to assess the relative clinical effectiveness of OHA and PI in a robust, sufficiently powered randomised controlled trial (RCT) in primary dental care.

The trial protocol was published in *BMC Oral Health* (Clarkson JE, Ramsay CR, Averley P, Bonetti D, Boyers D, Campbell L, *et al.* IQuaD dental trial; improving the quality of dentistry: a multicentre randomised controlled trial comparing oral hygiene advice and periodontal instrumentation for the prevention and management of periodontal disease in dentate adults attending dental primary care. *BMC Oral Health* 2013;**13**:58).

Objectives

The aim of this study was to compare the clinical effectiveness and cost-effectiveness of theory-based, personalised OHA or PI at different time intervals (no PI, 12-monthly PI or 6-monthly PI), or their combination (OHA and 6-monthly PI), with routine care for improving periodontal health in dentate adults attending general dental practice.

The primary objectives were to test the clinical effectiveness and cost-effectiveness of the following dental management strategies:

1. personalised OHA versus routine OHA
2. 6-monthly PI versus 12-monthly PI
3. 6-monthly PI versus no PI.

The secondary objectives were to:

1. test the clinical effectiveness and cost-effectiveness of a combination of personalised OHA with different time intervals for PI
2. measure dentist/hygienist beliefs relating to giving OHA, PI and maintenance of periodontal health.

Methods

Design

Improving the Quality of Dentistry (IQuaD) was a 5-year multicentre, pragmatic split-plot, cluster randomised, open trial with blinded outcome evaluation. The comparisons were made within a factorial design using a combination of cluster and individual participant randomisation. As personalised OHA was given by the dentist or hygienist, there was a theoretical risk of 'contamination' between patient participants seen within the same dental practice. To minimise this potential risk, dental practices were randomised to deliver routine or personalised OHA. All patient participants seen by the same dental practice (a 'cluster') received either routine (current practice) or personalised OHA, depending on their dental practice allocation. To test the effects of PI, each individual patient participant was randomised to no PI, 12-monthly PI or 6-monthly PI (current practice).

Setting

The trial recruited dental practitioners from general dental practices in Scotland and north-east England (Newcastle upon Tyne). Participating dentists represented a cross-section of practitioners operating in a range of different circumstances (e.g. urban or rural, high- to low-income communities, employing a dental hygienist or not).

Dentist participants

Inclusion criteria

- NHS provider for adult patients.
- Primary care provider.
- Willing to follow protocol.

Exclusion criteria

- Providing only private dental care.
- Unwilling to follow protocol.

Patient participants

Inclusion criteria

Adult patients (aged ≥ 18 years) with gingivitis or moderate periodontitis [a Basic Periodontal Examination (BPE) score of 0, 1, 2 or 3] who:

- were dentate
- had attended for a check-up at least twice in the previous 2 years
- received their dental care in part or in full as a NHS patient.

Exclusion criteria

- Patients with a BPE score of 4 (clinical probing depth of > 6 mm and/or furcation involvements or attachment loss of ≥ 7 mm) in any sextant on the basis that more extensive periodontal care was indicated.
- Patients with an uncontrolled chronic medical condition (e.g. diabetes mellitus, immunocompromised).

Interventions

Routine OHA was defined as the OHA currently being provided by the practices. There is no published information describing 'routine' OHA, but anecdotal evidence suggests that this is often the provision of minimal OHA (e.g. 'you need to brush your teeth more frequently') or no OHA.

The personalised OHA intervention was based on social cognitive theory and implementation intention theory. The content of the OHA delivered was personalised according to the dentist's/hygienist's assessment of the needs of the patient. At a minimum, the content included advice and instruction in self-diagnosis (e.g. bleeding gums on brushing indicates the presence of reversible gingival inflammation) and advice and instruction on tooth brushing and flossing (frequency and technique). On completion of the OHA, the dentist agreed an action plan with the patient.

The definition of PI was as used in standard practice and could include the removal of plaque and calculus from the crown and root surfaces using manual or ultrasonic scalers, with no adjunctive subgingival therapy (e.g. local delivery antibiotics), and the appropriate management of plaque retention factors.

Experimental groups received a PI at 6- or 12-monthly intervals according to the individual participant-level randomisation. Participants allocated to the no-PI groups attended their dentist at time intervals determined by current practice. However, participants and dental practices were advised that every trial participant should be invited to attend for a routine examination appointment at least every 12 months.

Main outcome measures

Primary outcomes

- Clinical: gingival inflammation/bleeding on probing at the gingival margin at the 3-year follow-up.
- Patient centred: oral hygiene self-efficacy at the 3-year follow-up.
- Economic: net benefits [mean willingness to pay (WTP) minus mean costs].

Secondary outcomes

- Clinical: (1) calculus, (2) clinical probing depth, (3) additional PI and (4) referral. (All of which were collected at the 3-year follow-up.)
- Patient centred: (1) dental quality of life, (2) oral health behaviour and (3) knowledge. (All of which were collected during 3 years' annual follow-up.)
- Economic: costs to the NHS and patients; WTP.
- Provider: beliefs relating to giving OHA and maintenance of periodontal health.

Note: the Periodontal Advisory Group considered that Clinical Attachment Loss and plaque cannot be measured reliably and so neither was included as outcomes.

Clinical outcomes were measured at baseline by trained outcome assessors (OAs) who were blinded to allocation. Gingival inflammation/bleeding scores, calculus, clinical probing depth and BPE scores were measured by the OAs and recorded on the baseline clinical chart by the dental research nurse, who was a member of the trial team. Patient-centred outcomes were measured at baseline and annually by self-administered postal questionnaire.

Economic evaluation

A within-trial cost–benefit analysis assessed the costs and benefits (in monetary terms) of each policy compared with standard care (routine OHA with 6-monthly PI). NHS and wider (NHS and participant) perspectives were considered.

Routinely collected dental claims data were linked to trial data to determine the costs of NHS-provided care (including participant co-charges). Additional participant costs, including private care, self-purchased products, and time and travel costs, were sourced from participant annual questionnaires.

A discrete choice experiment (DCE), administered to a nationally representative online sample of the UK general population, was used to estimate WTP. The design was pivoted and segmented to improve realism. DCE data were analysed using mixed logit regression models. WTP tariffs from the DCE were mapped to treatments received (PI and OHA), self-reported bleeding and aesthetics outcomes to calculate benefits.

The discount rate was 3.5%. Multilevel hierarchical models accounted for clustering, correlation between benefits and costs, and minimisation covariates. Results were presented as incremental net benefits, using confidence ellipses to illustrate uncertainty. Deterministic sensitivity analyses tested the impact of key assumptions on results. The fully approved protocol for the IQuaD trial can be accessed online via www.journalslibrary.nihr.ac.uk/programmes/hta/090145/#/ (accessed October 2017).

Results

A total of 2341 patients were screened for trial entry and 1877 participants were recruited. Of the screened patients, a total of 183 (8%) were found to be ineligible. The primary reason for ineligibility was a BPE score of 4 or * (furcation involvement), affecting 160 patients. From those ineligible because of a BPE score of 4 or *, 144 (90%) patients agreed to join a separate cohort group. There were 281 patients potentially eligible for the study who were not recruited.

At baseline, the mean number of teeth per participant was 24. Two-thirds of participants had a BPE score of ≤ 2 . The mean proportion of sites affected by bleeding was 33% and 35% of teeth had calculus present. The mean clinical probing depth was 1.8 mm. Between 10% and 12% of participants in each

group had four or more pockets with a clinical probing depth of ≥ 4 mm. There were no important imbalances across the randomised groups.

The pre-chosen clinical primary outcome was mean gingival inflammation/bleeding at 3 years' follow-up; 71% of the participants attended the 3-year clinical follow-up appointment. Under intention-to-treat (ITT) analysis, there was no evidence of a difference between those randomised to receive 6-monthly PI and those randomised to receive no PI [difference 0.87%, 95% confidence interval (CI) -1.6% to 3.3%; $p = 0.481$] (i.e. there was a $< 1\%$ difference in the average number of sites with gingival bleeding between the randomised groups). Similarly, there was no evidence of a difference between 6-monthly PI and 12-monthly PI (difference 0.11%, 95% CI -2.3% to 2.5%; $p = 0.929$). The 95% CIs were small enough to exclude the prespecified clinically important difference of 7.5% in bleeding. There was also no evidence of a difference between participants randomised to personalised OHA and those randomised to routine OHA (difference -2.5%, 95% CI -8.3% to 3.3%; $p = 0.393$). The results were robust to other adjusted/unadjusted models. The interaction between personalised OHA and 6-monthly PI was 1.7 (95% CI -3.8 to 7.3) (i.e. neither statistically nor clinically significant).

The pre-chosen patient-centred primary outcome was self-efficacy at the 3-year follow-up; 77% of the participants completed a 3-year questionnaire. Under ITT analysis, there was no evidence of a difference between those randomised to receive 6-monthly PI and those randomised to receive no PI (difference -0.028, 95% CI -0.119 to 0.063; $p = 0.543$). Between those randomised to receive 6-monthly and 12-monthly PI, there was a statistically significant difference at the 5% level favouring the 6-monthly PI (difference -0.097, 95% CI -0.188 to -0.006; $p = 0.037$); however, the size of the difference was not clinically important.

There were no significant differences in NHS dental costs. No PI with personalised OHA was the least costly policy (£62.42) [mean difference vs. standard care -£14.91 (95% CI -£15.70 to £28.16)], followed by no PI and routine OHA (£72.23) [mean difference -£3.12 (95% CI -£18.18 to £11.93)]. From a wider perspective, no PI with personalised OHA was significantly less costly [mean difference -£64.11 (95% CI -£112.33 to -£15.88)], followed by no PI with routine OHA [mean difference -£39.80 (95% CI -£83.94 to £4.33)].

The DCE showed that the general population valued both PI and personalised OHA even when controlling for bleeding and aesthetic outcomes. Therefore, 6-monthly PI with personalised OHA has the greatest benefit [mean difference vs. standard care £61.67 (95% CI £40.19 to £83.14)]. A 12-monthly PI with personalised OHA also had positive, but not significant, incremental benefits [mean difference £19.70 (95% CI -£1.64 to £41.04)]. This suggests that, in terms of WTP, a reduction in PI frequency can, in part, be compensated for by introducing personalised OHA.

Six-monthly PI with personalised OHA had the largest incremental net benefit compared with standard care from a NHS perspective [mean difference £48 (95% CI £22 to £74)] and a wider perspective [mean difference £68 (95% CI £15 to £120)]. The overall health economic results were broadly consistent across the UK countries and findings were robust to the sensitivity analyses undertaken.

Limitations

Being a pragmatic trial, we did not deny PIs to the no-PI group, although we did not collect detailed information about the reasons for additional PIs. However, there was clear separation in the mean number of PIs between groups. The economic evaluation was based on current NHS contracts that may change over time. A lifetime decision model was not conducted; however, given the lack of difference in clinical outcomes, extrapolation of trial results would be unlikely to change conclusions.

Conclusions

The IQuaD trial, involving regular adult NHS dental attenders (with no or early signs of periodontitis), has shown that, over a 3-year period, there is no additional benefit from scheduling 6-monthly or 12-monthly PIs over not providing this treatment unless desired or recommended, and that there is no difference between personalised or routine OHA (current practice) for the trial's primary clinical (gingival inflammation/bleeding) and patient-centred (self-reported) outcomes. However, patients value, and are willing to pay for, both interventions, with greater financial value placed on PI than on OHA.

Recommendations for research

- Research is needed to assess the clinical effectiveness and cost-effectiveness of providing multifaceted periodontal care packages (e.g. OHA, oral care-products, PI) in primary dental care for those with periodontitis.
- Research is required to better understand the source of WTP values and the extent to which this is influenced by perceptions and current practice.
- Research is needed to explore the relative value of different data sources for estimating resource use in dentistry including routine data, patient-reported data and practice records.

Trial registration

This trial is registered as ISRCTN56465715.

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